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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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John Babish

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28 STATE STREET
BOSTON, MA 02109-1775

EXAMINER

MELLER, MICHAEL V

ART UNIT

PAPER NUMBER

1655

NOTIFICATION DATE

DELIVERY MODE

11/23/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

BostonIPDocket@mwe.com

Office Action Summary	Application No. 10/557,293	Applicant(s) BABISH ET AL.	
	Examiner Michael V. Meller	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-10 and 12-41 is/are pending in the application.
- 4a) Of the above claim(s) 17-36 and 39-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-10, 12-16, 37, 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/3/07, 6/24/09, 7/2/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, in the reply filed on 5/12/2008 is acknowledged.
2. The requirement to the compounds and NSAIDs is withdrawn.
3. Claims 17-36, 39-41 are withdrawn from further consideration as being drawn to a non-elected invention (the method claims).

The requirement is still deemed proper and is therefore made FINAL.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 3-10, 12-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 2-9 of US Patent Application Number 11820600. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the application claims and/or discloses the claimed invention.

6. Claims 1, 3-10, 12-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 3-9 of US Patent Application Number 11820755. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant

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application are claiming common subject matter, as follows: the application claims and/or discloses the claimed invention.

7. Claims 1, 3-10, 12-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 3-13 of US Patent Application Number 11820621. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the application claims and/or discloses the claimed invention.

8. Claims 1, 3-10, 12-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-7, 9, 11-32 of US Patent Application Number 10789817. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the application claims and/or discloses the claimed invention.

9. Claims 1, 3-10, 12-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-3, 7, 10-15 of US Patent Application Number 11823934. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the application claims and/or discloses the claimed invention.

10. Claims 1, 3-10, 12-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 2-9 of US Patent Application Number 11820608. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the application claims and/or discloses the claimed invention.

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11. Claims 1, 3-10, 12-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 34-36, 38, 40-43 of US Patent Application Number 11355145. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the application claims and/or discloses the claimed invention.

12. Claims 1, 3-10, 12-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 17, 21-32 of US Patent Application Number 11355306. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the application claims and/or discloses the claimed invention.

13. Claims 1, 3-10, 12-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 1, 2, 10-15 of US Patent Application Number

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11326874. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the application claims and/or discloses the claimed invention.

14. Claims 1, 3-10, 12-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-3, 5-8, 10, 14-16 of US Patent Application Number 11820568. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the application claims and/or discloses the claimed invention.

15. Claims 1, 3-10, 12-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-8 of US Patent Application Number 11820607. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the application claims and/or discloses the claimed invention.

16. Claims 1, 3-10, 12-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-34 of US Patent Application Number 11501393. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the application claims and/or discloses the claimed invention.

17. Claims 1, 3-10, 12-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-34 of US Patent Application Number 11636867. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant

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application are claiming common subject matter, as follows: the application claims and/or discloses the claimed invention.

18. Claims 1, 3-10, 12-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 236, 238, 240-256 of US Patent Application Number 10532388. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the application claims and/or discloses the claimed invention.

19. Claims 1, 3-10, 12-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-31 of US Patent Application Number 11649584. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the application claims and/or discloses the claimed invention.

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20. Claims 1, 3-10, 12-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-32 of US Patent Application Number 10590424. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the application claims and/or discloses the claimed invention.

21. Claims 1, 3-10, 12-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-9 of US Patent Application Number 10590301. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the application claims and/or discloses the claimed invention.

22. Claims 1, 3-10, 12-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 2-9 of US Patent Application Number

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11820653. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the application claims and/or discloses the claimed invention.

23. Claims 1, 3-10, 12-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-34 of US Patent Application Number 12063039. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the application claims and/or discloses the claimed invention.

24. Claims 1, 3-10, 12-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-42 of US Patent Application Number 10866315. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

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The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the application claims and/or discloses the claimed invention.

If applicant is aware of any other applications/patents which would constitute an Obviousness type double patenting rejection (such as the ones above), applicant is required to put such evidence on the record and submit terminal disclaimers to obviate those applications/patent as well as the above listed ones.

Claim Rejections - 35 USC § 112

25. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

26. Claims 1, 3-10, 12-16, 37, 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a composition comprising a reduced isoalpha acid, dihydro isoalpha acid, tetra hydro isoalpha acid or hexahydro isoalpha acid along with a NSAID (non-aspirin, non-steroidal anti-inflammatory). Thus, the claims are drawn to a genus of compounds which are not completely quantifiable.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the only factor present in the claims is drawn to a composition comprising a reduced isoalpha acid, dihydroisoalpha acid, tetra hydro isoalpha acid or hexahydroisoalpha acid along with a NSAID. The specification appears to teach that specific reduced isoalpha acids such as tetrahydroisohumulones are

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known and certain NSAIDs such as ibuprofen are known but not any and all reduced isoalpha acids and NSAIDs. Accordingly, in the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus which encompassed by the claims as noted.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed.” (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of inhibitors, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See Fiers v. Revel, 25USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF's were found to

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be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, the full breadth of the claims does not meet the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Applicant argues that since a representative number of species have been described that applicant is entitled to any and all reduced iso alpha acids. Problem is, there are no other reduced iso alpha acids other than dihydroisohumulone (rho-isohumulone), tetrahydroisohumulone and hexahydroisohumulone described in the application or are known in the art (see enclosed De Keukeleire). What other reduced iso alpha acids is applicant envisioning ? It is simply not described in the application and the art teaches that these are the only known reduced isoalpha acids.

Claim Rejections - 35 USC § 103

27. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

28. Claims 1, 3-10, 12-16, 37, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhrts (US 20070003646) in view of Grattan (US 5866162).

Kuhrts teaches that reduced iso alpha acids such as dihydroisohumulones are known to be used to treat inflammation, see whole reference, especially paragraphs 32, 34, the claims. Note that 1-10 wt. % is used of the dihydroisohumulone.

Kuhrts does not teach using a NSAID, such as ibuprofen.

Grattan teaches that ibuprofen is known to be used to treat inflammation, see col. 1, lines 15-35.

It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Sussman*, 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943); *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). *In re Kerkhoven*, 626 F. 2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (It is *prima facie* obvious to combine two compositions

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each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose).

The reason or motivation to modify a reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. While there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention.

MPEP 2144 Sources of Rationale Supporting a Rejection Under 35 U.S.C. 103.
<http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2144.htm>

Thus, to use the ibuprofen and the dihydroisohumulone in the same composition to treat inflammation is obvious since they were both known in the art at the time the invention was made to be used for the same purpose, namely to treat inflammation.

Where the general conditions of the claims are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Selecting a narrow range within somewhat broader range is obvious:

Selecting a narrow range from within a somewhat broader range disclosed in a prior art reference is no less obvious than identifying a range that simply overlaps a disclosed range. In fact, when, as here, the claimed ranges are completely encompassed by the prior art, the conclusion is even more compelling than in cases of mere overlap. The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.

. . .

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We therefore conclude that a prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness. That is not to say that the claimed composition having a narrower range is unpatentable. Rather, the existence of overlapping or encompassing ranges shifts the burden to the applicant to show that his invention would not have been obvious, as we discuss below.

In re Peterson, 315 F.3d 1325, 1331 (Fed. Cir. 2003).

Thus, to use the claimed amounts in claims 7 and 8 is obvious since the dihydroisohumulone is clearly a results effective variable which was known for the desired effect of treating inflammation thus making it obvious to use the claimed amount to also treat inflammation since the dihydroisohumulone was known to be used to treat inflammation, thus making it obvious to use the claimed amounts for the same beneficial reason which is to treat inflammation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael V. Meller/
Primary Examiner, Art Unit 1655